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NOTICE OF ALLOWANCE AND FEE(S) DUE

21971 7590 10/06/2008 WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL, ROAD PALO ALTO, CA 94304-1050 EXAMINER

BRISTOL, LYNN ANNE

ART UNIT PAPER NUMBER

DATE MAILED: 10/06/2008

 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNEY DOCKET NO.
 CONFREMATION NO.

 10/527,257
 03/09/2005
 Jun Wu
 34569-714.831
 5292

TITLE OF INVENTION: TUMOR TAG AND THE USE THEREOF

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	01/06/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT, PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This f appropriate. All further c indicated unless corrected maintenance fee notification	form should be used for or spondence including the low or directed others.	or trang the	nsmitting the ISSU Patent, advance on in Block 1, by (a					hould be completed where correspondence address as arate "FEE ADDRESS" for
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				[(Depositor's name)
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APPLICATION NO.	FILING DATE			FIRST NAMED INVENT	OR	ATT	ORNEY DOCKET NO.	CONFIRMATION NO.
10/527,257	03/09/2005			Jun Wu	34569-714.831			5292
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nonprovisional	YES		\$755	\$300	\$0		\$1055	01/06/2009
EXAMI	NER		ART UNIT	CLASS-SUBCLASS				
BRISTOL, LY	'NN ANNE		1643	514-012000				
	ndence address (or Cha 122) attached. atton (or "Fee Address" or more recent) attach ID RESIDENCE DATA ss an assignee is identi in 37 CFR 3.11. Comp	nge of 'Indiced. Us	Correspondence ation form e of a Customer	data will appear on th T a substitute for filing	to 3 registered p atively, agle firm (having or agent) and the attorneys or agents be printed. type) patent. If an as- an assignment.	as a mem names of . If no na rignee is	ber a 2up to me is 3identified below, the d	ocument has been filed for
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4a. The following fee(s) are submitted: Issue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies				A. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) A check is enclosed. Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpoyment, to Depoint Account Number (enclose an extra copy of this form).				
 Change in Entity Statu a. Applicant claims 	SMALL ENTITY statu	s. See	37 CFR 1.27.	☐ b. Applicant is no	onger claiming S!	MALL EN	TITY status. Sec 37 C	FR 1.27(g)(2).
NOTE: The Issue Fee and interest as shown by the re	Publication Fee (if requeends of the United Sta	ired) tes Pat	will not be accepted ent and Trademark	d from anyone other that Office.	n the applicant; a	registered	l attorney or agent; or the	ne assignee or other party in
Authorized Signature _					Date			
Typed or printed name				Registration No.				
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650 PAGE MILL		ART UNIT	PAPER NUMBER		
PALO ALTO, CA	4 94304-1050	1643			

DATE MAILED: 10/06/2008

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 152 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 152 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/527.257 WU ET AL. Notice of Allowability Examiner Art Unit LYNN BRISTOL 1643 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to the Response of 7/23/08. The allowed claim(s) is/are 1-8, 14 and 15. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date 3. Information Disclosure Statements (PTO/SB/08), 7. X Examiner's Amendment/Comment Paper No./Mail Date 4. T Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material Other . /David J Blanchard/

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-06)

Primary Examiner, Art Unit 1643

Art Unit: 1643

DETAILED ACTION

1. Claims 1-8, 14 and 15 are all the pending claims for this application.

Claim 3 was amended in the Response of 7/23/08.

3. Claims 1-8, 14 and 15 are all the pending claims under examination.

Withdrawal of Rejections

Claim Rejections - 35 USC § 112, second paragraph

- 4. Claims 3-8, 14 and 15 were rejected for reciting the limitation "polynucleotide" in the preamble and in element c) of Claim 3, and Claims 4-8, 14 and 15 were rejected for reciting or incorporating "the polynucleotide of Claim 3". Claim 3 was also rejected for reciting "a nucleotide" in elements a) and b). The claims were amended to correct the antecedency within Claim 3 and which corrects the antecedany with respect to Claims 4-8, 14 and 15.
- 5. The rejection of Claims 3-8, 14 and 15 for the recitation "hybridizes under stringent conditions" in element c) of Claim 3 because the exact conditions are not defined (or clearly supported) in the specification is withdrawn. Claim 3 has been amended to delete the recitation for the hybridization conditions.

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Claim Rejections - 35 USC § 112, first paragraph

Written Description

6. The rejection of Claims 3-8, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because Claims 3-8, 14 and 15 encompass a polynucleotide sequence comprising an antisense strand which is able to hybridize to a nucleotide sequence of element a) or b) of Claim 3, and which also encodes a polypeptide having the same biological function or activity as the RL5 protein of SEQ ID NO:2 or residues 29-213 of SEQ ID NO:2, is withdrawn.

Applicants have amended Claim 3 to delete element c) which meets and overcomes the rejection.

EXAMINER'S AMENDMENT

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael HOSTETLER on 9/25/08.

Claim 8 (currently amended) A method for producing RL5, protein which comprises:

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(a) culturing the host cell of Claim 7 under expression conditions for the vector of Claim 6 an isolated genetically engineered host cell comprising the vector of Claim 6, thereby expressing RL5 protein in a culture of the host cells of Claim 7; and

(b) isolating RL5 protein from the culture of step (a).

STATEMENT OF REASONS FOR ALLOWANCE

8. The following is an examiner's statement of reasons for allowance:

The RL5 protein comprising the amino acid sequence of SEQ ID NO:2 (mature polypeptide) and residues 29-213 of SEQ ID NO:2 (mature RL5 minus residues 1-28 for the signal peptide) is free of prior art. The polynucleotide of residues 85-639 of SEQ ID NO:1 (ORF minus residues 1-84 encoding the signal peptide); residues 1-639 of SEQ ID NO:1 (ORF); and SEQ ID NO:1 (residues 1-720 of the DNA fragment) and all of which encode the RL5 protein is free of prior art.

The closest art for a protein sequence or polynucleotide sequence having 100% sequence identity to the invention is the following:

- a) Hood et al., U.S. Provisional 60/836,968 (filed 8/9/06)- see attached sequence alignments for SEQ ID NO:1 and SEQ ID NO:2;
- b) Trowsdale et al., U.S. 10/589, 851 (filed 2/17/05)- see attached sequence search for SEQ ID NO:1:
- c) Harkin et al., U.S. 11/266,748 (filed11/3/05)- see attached sequence search for SFO ID NO:1

The references each have a post-filing date against the priority filing date (9/9/02) for the instant claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

- Claims 1-8, 14 and 15 are in condition for allowance.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/David J Blanchard/ Primary Examiner, Art Unit 1643